201-16041

IUCLID

Data Set

Existing Chemical	:	ID: 57-11-4
EINECS Name	:	stearic acid
EC No.	:	200-313-4
Molecular Formula	:	C18H36O2

Producer related part

Company	:	Epona Associates, LLC
Creation date	:	04.12.2003

Substance related part

Company	:	Epona Associates, LLC
Creation date	:	04.12.2003
Status	:	
Memo	:	SOCMA MCC
Printing date	:	05.12.2003
Revision date	:	
Date of last update	:	05.12.2003
Number of pages	:	22
Chapter (profile)	:	Chapter: 1, 2, 3, 4, 5, 6, 7, 8, 10
Reliability (profile)	:	Reliability: without reliability, 1, 2, 3, 4
Flags (profile)	:	Flags: without flag, confidential, non confidential, WGK (DE), TA-Luft (DE), Material Safety Dataset, Risk Assessment, Directive 67/548/EEC, SIDS

1.0.1 APPLICANT AND COMPANY INFORMATION

1.0.2 LOCATION OF PRODUCTION SITE, IMPORTER OR FORMULATOR

1.0.3 IDENTITY OF RECIPIENTS

1.0.4 DETAILS ON CATEGORY/TEMPLATE

1.1.0 SUBSTANCE IDENTIFICATION

1.1.1 GENERAL SUBSTANCE INFORMATION

Purity type	:	
Substance type	:	organic
Physical status	:	solid
Purity	:	-
Colour	:	Colorless, waxy solid
Odour	:	SLIGHT TALLOW-LIKE ODOR
Source	:	Epona Associates, LLC
Reliability	:	(2) valid with restrictions Information taken from a peer-reviewed publication.

04.12.2003 (5)

04.12.2003

1.1.2 SPECTRA

1.2 SYNONYMS AND TRADENAMES

1.3 IMPURITIES

1.4 ADDITIVES

1.5 TOTAL QUANTITY

1.6.1 LABELLING

1.6.2 CLASSIFICATION

1.6.3 PACKAGING

1.7 USE PATTERN

1.7.1 DETAILED USE PATTERN

1.7.2 METHODS OF MANUFACTURE

1.8 REGULATORY MEASURES

Type of measure :
Legal basis : other: Generally Recognized as Safe

Remark : [Code of Federal Regulations]
[Title 21, Volume 3]
[Revised as of April 1, 2003]
From the U.S. Government Printing Office via GPO Access
[CITE: 21CFR184.1090]

TITLE 21--FOOD AND DRUGS

CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
PART 184--DIRECT FOOD SUBSTANCES AFFIRMED AS GENERALLY RECOGNIZED AS SAFE

Subpart B--Listing of Specific Substances Affirmed as GRAS

Sec. 184.1090 Stearic acid.

(a) Stearic acid (C16H36O2, CAS Reg. No. 57-11-4) is a white to yellowish white solid. It occurs naturally as a glyceride in tallow and other animal or vegetable fats and oils and is a principal constituent of most commercially hydrogenated fats. It is produced commercially from hydrolyzed tallow derived from edible sources or from hydrolyzed, completely hydrogenated vegetable oil derived from edible sources.

(b) The ingredient meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), p. 313, which is incorporated by reference, and the requirements of Sec. 172.860(b)(2) of this chapter. Copies of the Food Chemicals Codex are available from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC 20408.

(c) In accordance with Sec. 184.1(b)(1), the ingredient is used in food with no limitation other than current good manufacturing practice. The affirmation of this ingredient as generally recognized as safe (GRAS) as a direct human food ingredient is based upon the following current good manufacturing practice conditions of use:

(1) The ingredient is used as a flavoring agent and adjuvant as

defined in Sec. 170.3(o)(12) of this chapter.
(2) The ingredient is used in foods at levels not to exceed current good manufacturing practice.
(d) Prior sanctions for this ingredient different from the uses established in this section do not exist or have been waived.

[48 FR 52445, Nov. 18, 1983, as amended at 50 FR 49536, Dec. 3, 1985]

Reliability : (1) valid without restriction
05.12.2003

1.8.1 OCCUPATIONAL EXPOSURE LIMIT VALUES

1.8.2 ACCEPTABLE RESIDUES LEVELS

1.8.3 WATER POLLUTION

1.8.4 MAJOR ACCIDENT HAZARDS

1.8.5 AIR POLLUTION

1.8.6 LISTINGS E.G. CHEMICAL INVENTORIES

1.9.1 DEGRADATION/TRANSFORMATION PRODUCTS

1.9.2 COMPONENTS

1.10 SOURCE OF EXPOSURE

1.11 ADDITIONAL REMARKS

1.12 LAST LITERATURE SEARCH

1.13 REVIEWS

2.1 MELTING POINT

Value	:	= 69 - 70 °C
Sublimation	:	
Method	:	
Year	:	1982
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	Epona Associates, LLC
Reliability	:	(2) valid with restrictions Information taken from a peer-reviewed publication.
Flag	:	Critical study for SIDS endpoint

04.12.2003 (16)

2.2 BOILING POINT

Value	:	= 383 - °C at 1013 hPa
Decomposition	:	
Method	:	
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	Epona Associates, LLC
Reliability	:	(2) valid with restrictions Information taken from a peer-reviewed publication.
Flag	:	Critical study for SIDS endpoint

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2.3 DENSITY

2.3.1 GRANULOMETRY

2.4 VAPOUR PRESSURE

Value	:	= 1.33 - hPa at 173.7 °C
Decomposition	:	
Method	:	
Year	:	1969
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	Epona Associates, LLC
Reliability	:	(2) valid with restrictions Information taken from a peer-reviewed publication.
Flag	:	Critical study for SIDS endpoint

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2.5 PARTITION COEFFICIENT

Partition coefficient	:	octanol-water
Log pow	:	= 8.42 - at °C
pH value	:	-
Method	:	
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	Epona Associates, LLC
Reliability	:	(2) valid with restrictions Information taken from a peer-reviewed publication.

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2.6.1 SOLUBILITY IN DIFFERENT MEDIA

Solubility in	:	Water
Value	:	= .568 - mg/l at 25 °C
pH value	:	-
concentration	:	at °C
Temperature effects	:	
Examine different pol.	:	
pKa	:	at 25 °C
Description	:	
Stable	:	
Deg. product	:	
Method	:	other: measured
Year	:	1966
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Result	:	Water solubility = .0001 mg/L at 30 deg C
Reliability	:	(2) valid with restrictions Information taken from a peer-reviewed publication.

05.12.2003 (12)

2.6.2 SURFACE TENSION

2.7 FLASH POINT

2.8 AUTO FLAMMABILITY

2.9 FLAMMABILITY

2.10 EXPLOSIVE PROPERTIES

2.11 OXIDIZING PROPERTIES

2.12 DISSOCIATION CONSTANT

2.13 VISCOSITY

2.14 ADDITIONAL REMARKS

3.1.1 PHOTODEGRADATION

Type	:	air
Light source	:	
Light spectrum	:	- nm
Relative intensity	:	- based on intensity of sunlight
DIRECT PHOTOLYSIS		
Halflife t1/2	:	= .5 - day(s)
Degradation	:	- % after
Quantum yield	:	
Deg. product	:	
Method	:	other (calculated)
Year	:	2003
GLP	:	no
Test substance	:	as prescribed by 1.1 - 1.4
Method	:	Estimated using AopWin v1.91
Result	:	Atmospheric Oxidation (25 deg C) [AopWin v1.91]: Hydroxyl Radicals Reaction: OVERALL OH Rate Constant = 22.4804 E-12 cm3/molecule-sec Half-Life = 0.476 Days (12-hr day; 1.5E6 OH/cm3) Half-Life = 5.710 Hrs Ozone Reaction: No Ozone Reaction Estimation
Source	:	Epona Associates, LLC
Reliability	:	(2) valid with restrictions
Flag	:	Critical study for SIDS endpoint

04.12.2003

Type	:	air
Light source	:	
Light spectrum	:	- nm
Relative intensity	:	- based on intensity of sunlight
DIRECT PHOTOLYSIS		
Halflife t1/2	:	= 17 - hour(s)
Degradation	:	- % after
Quantum yield	:	
Deg. product	:	
Method	:	
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Result	:	Vapor phase stearic acid is degraded in the atmosphere by reaction with photochemically-produced hydroxyl radicals with a half-life of about 17 hours.
Source	:	Epona Associates, LLC
Reliability	:	(2) valid with restrictions Information taken from a peer-reviewed publication.

05.12.2003 (1) (3) (6) (10)

3.1.2 STABILITY IN WATER

3.1.3 STABILITY IN SOIL

3.2.1 MONITORING DATA

3.2.2 FIELD STUDIES

3.3.1 TRANSPORT BETWEEN ENVIRONMENTAL COMPARTMENTS

Type	:	fugacity model level III
Media	:	
Air	:	% (Fugacity Model Level I)
Water	:	% (Fugacity Model Level I)
Soil	:	% (Fugacity Model Level I)
Biota	:	% (Fugacity Model Level II/III)
Soil	:	% (Fugacity Model Level II/III)
Method	:	other: modeling
Year	:	2003
Method	:	EPI v3.11
Result	:	Level III Fugacity Model:

	Mass Amount (percent)	Half-Life (hr)	Emissions (kg/hr)
Air	0.676	11.4	1000
Water	7.19	360	1000
Soil	28.9	360	1000
Sediment	63.3	1.44e+003	0

Persistence Time: 640 hr

Source	:	Epona Associates, LLC
Reliability	:	(2) valid with restrictions
Flag	:	Critical study for SIDS endpoint

04.12.2003

3.3.2 DISTRIBUTION

3.4 MODE OF DEGRADATION IN ACTUAL USE

3.5 BIODEGRADATION

Type	:	aerobic
Inoculum	:	activated sludge
Contact time	:	
Degradation	:	= 77 - (±) % after 28 day(s)
Result	:	readily biodegradable
Kinetic of testsubst.	:	10 day(s) = 65 - % 14 day(s) = 69 - % 28 day(s) = 77 - % - % - %
Deg. product	:	
Method	:	other: BOD test
Year	:	1983
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Remark	:	Results are an average of 11 participating laboratories.

Result	:	65, 69 and 77 % degradation after 10, 14 and 28 days, respectively.
Source	:	Epona Associates, LLC
Reliability	:	(2) valid with restrictions Information taken from a peer-reviewed publication.
05.12.2003		(7)

Type	:	aerobic
Inoculum	:	activated sludge
Concentration	:	100 g/l related to Test substance related to
Contact time	:	5 day(s)
Degradation	:	- (±) % after
Result	:	readily biodegradable
Deg. product	:	
Method	:	other: BOD5
Year	:	1985
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Result	:	Rate: .0088 1/HR Half-Life [Days]: 3.3
Source	:	Epona Associates, LLC
Test condition	:	BOD test conducted at 20 deg C.
Reliability	:	(2) valid with restrictions Information taken from a peer-reviewed publication.
05.12.2003		(14)

Type	:	aerobic
Inoculum	:	other: sewage sludge
Contact time	:	21 day(s)
Degradation	:	= 95 - (±) % after 21 day(s)
Result	:	readily biodegradable
Deg. product	:	
Method	:	other: Sturm CO2 evolution
Year	:	1984
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	Epona Associates, LLC
Reliability	:	(2) valid with restrictions Information taken from a peer-reviewed publication.
Flag	:	Critical study for SIDS endpoint
05.12.2003		(13)

Type	:	aerobic
Inoculum	:	activated sludge
Contact time	:	
Degradation	:	- (±) % after
Result	:	readily biodegradable
Deg. product	:	
Method	:	other: Warburg
Year	:	1973
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Result	:	Rate: .0077; .0052; .00217 Rate Units: 1/HR Half-Life [Days]: 3.75; 5.55; 10.7
Source	:	Epona Associates, LLC

Test condition	:	Test Method: WARBURG Oxygen Condition: AEROBIC Analysis Method: 02 UPTAKE Inoculum: ACTIVATED SLUDGE Temperature [øC]: 20; 25; 30
Reliability	:	(2) valid with restrictions Information taken from a peer-reviewed publication.

05.12.2003 (11)

3.6 BOD5, COD OR BOD5/COD RATIO

3.7 BIOACCUMULATION

3.8 ADDITIONAL REMARKS

4.1 ACUTE/PROLONGED TOXICITY TO FISH

Type	:	static
Species	:	Oncorhynchus kisutch (Fish, fresh water, marine)
Exposure period	:	> 96 hour(s)
Unit	:	µg/l
LC50	:	= 12000 - measured/nominal
Method	:	The test result is actually LT50 not LC50
Year	:	1977
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	Epona Associates, LLC
Test substance	:	"pure"
Reliability	:	(2) valid with restrictions
Flag	:	Critical study for SIDS endpoint

05.12.2003 (8)

4.2 ACUTE TOXICITY TO AQUATIC INVERTEBRATES

4.3 TOXICITY TO AQUATIC PLANTS E.G. ALGAE

4.4 TOXICITY TO MICROORGANISMS E.G. BACTERIA

4.5.1 CHRONIC TOXICITY TO FISH

4.5.2 CHRONIC TOXICITY TO AQUATIC INVERTEBRATES

4.6.1 TOXICITY TO SEDIMENT DWELLING ORGANISMS

4.6.2 TOXICITY TO TERRESTRIAL PLANTS

4.6.3 TOXICITY TO SOIL DWELLING ORGANISMS

4.6.4 TOX. TO OTHER NON MAMM. TERR. SPECIES

4.7 BIOLOGICAL EFFECTS MONITORING

4.8 BIOTRANSFORMATION AND KINETICS

4.9 ADDITIONAL REMARKS

5.0 TOXICOKINETICS, METABOLISM AND DISTRIBUTION

5.1.1 ACUTE ORAL TOXICITY

Type	:	LD50
Value	:	= 4600 - mg/kg bw
Species	:	rat
Strain	:	
Sex	:	
Number of animals	:	
Vehicle	:	
Doses	:	
Method	:	
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Source	:	Epona Associates, LLC
Reliability	:	(2) valid with restrictions Information taken from a peer-reviewed publication.

05.12.2003 (2)

Type	:	LD100
Value	:	= 14286 - mg/kg bw
Species	:	human
Strain	:	
Sex	:	
Number of animals	:	
Vehicle	:	
Doses	:	
Method	:	
Year	:	1976
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Result	:	Minimum/Potential Fatal Human Dose: 1. 1= PRACTICALLY NONTOXIC: PROBABLE ORAL LETHAL DOSE (HUMAN) MORE THAN 1 QT (2.2 LB) FOR 70 KG PERSON (150 LB).
Source	:	Epona Associates, LLC
Reliability	:	(2) valid with restrictions Information taken from a peer-reviewed publication.

05.12.2003 (4)

5.1.2 ACUTE INHALATION TOXICITY

5.1.3 ACUTE DERMAL TOXICITY

5.1.4 ACUTE TOXICITY, OTHER ROUTES

5.2.1 SKIN IRRITATION

5.2.2 EYE IRRITATION

5.3 SENSITIZATION

5.4 REPEATED DOSE TOXICITY

Type	:	Sub-chronic
Species	:	rat
Sex	:	
Strain	:	
Route of admin.	:	oral feed
Exposure period	:	24 weeks
Frequency of treatm.	:	
Post exposure period	:	
Doses	:	50g/kg/day
Control group	:	
Method	:	
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Result	:	Rats fed 50 g/kg/day stearic acid for 24 weeks developed reversible lipogranulomas in adipose tissue. No significant pathological lesions were observed in rats fed 3000 ppm stearic acid orally for about 30 weeks, but anorexia, increased mortality, and a greater incidence of pulmonary infection were observed. Stearic acid is one of the least effective fatty acids in producing hyperlipemia, but the most potent in diminishing blood clotting time.
Source	:	Epona Associates, LLC
Reliability	:	(2) valid with restrictions Information taken from a peer-reviewed publication.

05.12.2003 (2)

Type	:	Sub-acute
Species	:	rat
Sex	:	
Strain	:	
Route of admin.	:	oral feed
Exposure period	:	6 or 9 weeks
Frequency of treatm.	:	
Post exposure period	:	
Doses	:	5 or 6%
Control group	:	
Result	:	Rats fed 5% stearic acid as part of a high-fat diet for 6 weeks, or 6% stearic acid for 9 weeks, showed a decreased blood clotting time and hyperlipemia.
Source	:	Epona Associates, LLC
Reliability	:	(2) valid with restrictions Information taken from a peer-reviewed publication.

05.12.2003

Type	:	Sub-acute
Species	:	mouse

Sex	:	
Strain	:	
Route of admin.	:	oral feed
Exposure period	:	3 weeks
Frequency of treatm.	:	
Post exposure period	:	
Doses	:	5 to 50%
Control group	:	
Method	:	
Year	:	
GLP	:	no data
Test substance	:	as prescribed by 1.1 - 1.4
Result	:	When diets containing 5 to 50% stearic acid (as the monoglyceride) were fed to weanling mice for 3 weeks, depression of weight gain was seen above the 10% dietary level. Mortality occurred only with the 50% diet. The effects were less noticeable in adult mice.
Source	:	Epona Associates, LLC
Reliability	:	(2) valid with restrictions Information taken from a peer-reviewed publication.

05.12.2003 (2)

5.5 GENETIC TOXICITY 'IN VITRO'

5.6 GENETIC TOXICITY 'IN VIVO'

5.7 CARCINOGENICITY

5.8.1 TOXICITY TO FERTILITY

5.8.2 DEVELOPMENTAL TOXICITY/TERATOGENICITY

5.8.3 TOXICITY TO REPRODUCTION, OTHER STUDIES

5.9 SPECIFIC INVESTIGATIONS

5.10 EXPOSURE EXPERIENCE

5.11 ADDITIONAL REMARKS

6.1 ANALYTICAL METHODS

6.2 DETECTION AND IDENTIFICATION

7.1 FUNCTION

7.2 EFFECTS ON ORGANISMS TO BE CONTROLLED

7.3 ORGANISMS TO BE PROTECTED

7.4 USER

7.5 RESISTANCE

8.1 METHODS HANDLING AND STORING

8.2 FIRE GUIDANCE

8.3 EMERGENCY MEASURES

8.4 POSSIB. OF RENDERING SUBST. HARMLESS

8.5 WASTE MANAGEMENT

8.6 SIDE-EFFECTS DETECTION

8.7 SUBSTANCE REGISTERED AS DANGEROUS FOR GROUND WATER

8.8 REACTIVITY TOWARDS CONTAINER MATERIAL

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10.1 END POINT SUMMARY

10.2 HAZARD SUMMARY

10.3 RISK ASSESSMENT

Final Submission for Tall Oil Fatty Acids and Related Substances

Pine Chemicals Association
August 2004

VII. Robust Summaries of Data for Tall Oil Fatty Acids and Related Substances

PHYSICO-CHEMICAL PROPERTY – WATER SOLUBILITY	
Test Substance	
Chemical Name	Tall oil fatty acid
CAS #	61790-12-3
Remarks	This substance is also referred to as TOFA in the Final Data Summary for Tall Oil Fatty Acids and Related Substances.
Method	
Method/Guideline followed	Testing was conducted according to OECD Test Method 105, Water Solubility
Test Type	Water solubility
GLP (Y/N)	Y
Year (Study Performed)	2003
Test conditions	Tall oil fatty acid (TOFA) was tested for water solubility by weighing 0.5 g of the test material into an Erlenmeyer flask and adding 120 to 150 ml of Milli-Q water. Samples were prepared in triplicate. The flasks were then shaken orbitally at 150 r.p.m. at 30 ^{0}C ± 1 ^{0}C for 72 h. A Milli-Q water blank was prepared in the same manner, without test material. At the end of the shaking period, the flasks were transferred to a water bath at 20 ^{0}C ± 1 ^{0}C for 24 h. 100 ml of the clear supernatant/filtrate was then adjusted to pH2 with phosphoric acid and extracted using solid phase extraction cartridges, evaporated to residue, reconstituted in an internal standard solution and derivatized with trimethylphenylammonium hydroxide (TMPAH). The test samples were then assayed by gas chromatography (GC) using flame ionization detection (FID). Myristic acid methyl ester was used as the internal standard.
Results	The water solubility of tall oil fatty acid, in its entirety as a complex mixture, is 12.6 mg/l at 20 ^{0}C.
Data Quality	Reliable without restrictions – Klimisch Code 1a
References	Dinwoodie, N.B. 2003. Determination of the Water Solubility of Tall Oil Fatty Acids and Related Products. Report No. 23304, Inveresk Research, Tranent, Scotland.

PHYSICO-CHEMICAL PROPERTY – WATER SOLUBILITY	
Test Substance	
Chemical Name	Fatty acids, tall oil, low boiling
CAS #	65997-03-7
Remarks	This substance is also referred to as tall oil heads in the Final Data Summary for Tall Oil Fatty Acids and Related Substances.
Method	
Method/Guideline followed	Testing was conducted according to OECD Test Method 105, Water Solubility
Test Type	Water solubility
GLP (Y/N)	Y

Year (Study Performed)	2003
Test conditions	Fatty acids, tall oil, low boiling was tested for water solubility by weighing 0.5 g of the test material into an Erlenmeyer flask and adding 120 to 150 ml of Milli-Q water. Samples were prepared in triplicate. The flasks were then shaken orbitally at 150 r.p.m. at 30 ^{0}C ± 1 ^{0}C for 72 h. A Milli-Q water blank was prepared in the same manner, without test material. At the end of the shaking period, the flasks were transferred to a water bath at 20 ^{0}C ± 1 ^{0}C for 24 h. 100 ml of the clear supernatant/filtrate was then adjusted to pH2 with phosphoric acid and extracted using solid phase extraction cartridges, evaporated to residue, reconstituted in an internal standard solution and derivatized with trimethylphenylammonium hydroxide (TMPAH). The test samples were then assayed by gas chromatography (GC) using flame ionization detection (FID). Myristic acid methyl ester was used as the internal standard.
Results	The water solubility of fatty acids, tall oil, low boiling, in its entirety as a complex mixture, is 22.8 mg/l at 20 ^{0}C.
Data Quality	Reliable without restrictions – Klimisch Code 1a
References	Dinwoodie, N.B. 2003. Determination of the Water Solubility of Tall Oil Fatty Acids and Related Products. Report No. 23304, Inveresk Research, Tranent, Scotland.

PHYSICO-CHEMICAL PROPERTY – WATER SOLUBILITY	
Test Substance	
Chemical Name	Fatty acids, C16-C18 and C18 unsaturated, branched and linear
CAS #	68955-98-6
Remarks	This substance is also referred to as monomer acid in the Final Data Summary for Tall Oil Fatty Acids and Related Substances.
Method	
Method/Guideline followed	Testing was conducted according to OECD Test Method 105, Water Solubility
Test Type	Water solubility
GLP (Y/N)	Y
Year (Study Performed)	2003
Test conditions	Monomer acid was tested for water solubility by weighing 0.5 g of the test material into an Erlenmeyer flask and adding 120 to 150 ml of Milli-Q water. Samples were prepared in triplicate. The flasks were then shaken orbitally at 150 r.p.m. at 30 ^{0}C ± 1 ^{0}C for 72 h. A Milli-Q water blank was prepared in the same manner, without test material. At the end of the shaking period, the flasks were transferred to a water bath at 20 ^{0}C ± 1 ^{0}C for 24 h. 100 ml of the clear supernatant/filtrate was then adjusted to pH2 with phosphoric acid and extracted using solid phase extraction cartridges, evaporated to residue, reconstituted in an internal standard solution and derivatized with trimethylphenylammonium hydroxide (TMPAH). The test samples were then assayed by gas chromatography (GC) using flame ionization detection (FID). Myristic acid methyl ester was used as the internal standard.

Results	The water solubility of monomer acid, in its entirety as a complex mixture, is 15.0 mg/l at 20 ^{0}C.
Data Quality	Reliable without restrictions – Klimisch Code 1a
References	Dinwoodie, N.B. 2003. Determination of the Water Solubility of Tall Oil Fatty Acids and Related Products. Report No. 23304, Inveresk Research, Tranent, Scotland.

PHYSICO-CHEMICAL PROPERTY – WATER SOLUBILITY	
Test Substance	
Chemical Name	Octadecanoic acid, branched and linear
CAS #	68201-37-6
Remarks	This substance is also referred to as hydrogenated monomer acid in the Final Data Summary for Tall Oil Fatty Acids and Related Substances.
Method	
Method/Guideline followed	Testing was conducted according to OECD Test Method 105, Water Solubility
Test Type	Water solubility
GLP (Y/N)	Y
Year (Study Performed)	2003
Test conditions	Octadecanoic acid, branched and linear was tested for water solubility by weighing 0.5 g of the test material into an Erlenmeyer flask and adding 120 to 150 ml of Milli-Q water. Samples were prepared in triplicate. The flasks were then shaken orbitally at 150 r.p.m. at 30 ^{0}C ± 1 ^{0}C for 72 h. A Milli-Q water blank was prepared in the same manner, without test material. At the end of the shaking period, the flasks were transferred to a water bath at 20 ^{0}C ± 1 ^{0}C for 24 h. 100 ml of the clear supernatant/filtrate was then adjusted to pH2 with phosphoric acid and extracted using solid phase extraction cartridges, evaporated to residue, reconstituted in an internal standard solution and derivatized with trimethylphenylammonium hydroxide (TMPAH). The test samples were then assayed by gas chromatography (GC) using flame ionization detection (FID). Myristic acid methyl ester was used as the internal standard.
Results	The water solubility of octadecanoic acid, branched and linear, in its entirety as a complex mixture, is 2.5 mg/l at 20 ^{0}C.
Data Quality	Reliable without restrictions – Klimisch Code 1a
References	Dinwoodie, N.B. 2003. Determination of the Water Solubility of Tall Oil Fatty Acids and Related Products. Report No. 23304, Inveresk Research, Tranent, Scotland.

PHYSICO-CHEMICAL PROPERTY – OCTANOL/WATER PARTITION COEFFICIENT	
Test Substance	
Chemical Name	Tall oil fatty acid
CAS #	61790-12-3
Remarks	This substance is also referred to as TOFA in the Final Data Summary for Tall Oil Fatty Acids and Related Substances.
Method	
Method/Guideline followed	Testing was conducted according to OECD Test Method 117, *"Partition Coefficient (n-Octanol/Water) High Performance Liquid Chromatograph (HPLC) Method"*

Test Type	Partition coefficient
GLP (Y/N)	Y
Year (Study Performed)	2002
Test conditions	Tall oil fatty acid and reference materials were dissolved in methanol and the solutions were analyzed in duplicate by HPLC with Refractive Index (RI) and Photodiode Array (PDA) detection using a mobile phase of 25:75 (v/v) Milli-Q water/methanol at pH 2. A mixture of seven materials with known log P_{ow} values was used for reference.
Results	At pH 2, tall oil fatty acid had a partition coefficient range of 4.9 to 7.6.
Data Quality	Reliable without restrictions – Klimisch Code 1a
Reference	Lightbody, S.M., Fisher, K. and Dinwoodie, N.B. 2002. Determination of the Partition Coefficient of Fatty Acids and Fatty Acid Salts. Report No. 20976. Inveresk Research, Tranent, Scotland.

PHYSICO-CHEMICAL PROPERTY – OCTANOL/WATER PARTITION COEFFICIENT	
Test Substance	
Chemical Name	Tall oil fatty acid
CAS #	61790-12-3
Remarks	This substance is also referred to as TOFA in the Final Data Summary for Tall Oil Fatty Acids and Related Substances.
Method	
Method/Guideline followed	Testing was conducted according to OECD Test Method 117, *"Partition Coefficient (n-Octanol/Water) High Performance Liquid Chromatograph (HPLC) Method"*
Test Type	Partition coefficient
GLP (Y/N)	Y
Year (Study Performed)	1993
Test conditions	Tall oil fatty acid was dissolved in methanol and the solution was analyzed by HPLC with UV detection using a mobile phase of methanol:buffer (3:1) at pH 2 and pH 7.5. A mixture of seven materials with known log P_{ow} values was used for reference.
Results	At pH 2, the log P_{ow} values of seven components in tall oil fatty acid were 4.4, 7.0, 7.3, 7.5, 7.7, 8.0, and 8.3. At pH 7.5, the log K_{ow} values of six components in tall oil fatty acid were 3.6, 3.8, 4.2, 4.5, 4.7, and 7.4.
Data Quality	Reliable without restrictions – Klimisch Code 1a
Reference	Dybdahl, H.P. 1993. Determination of log P_{ow} for single components in tall oil fatty acid. GLP Study No. 408335/472. Water Quality Institute, Horsh□lm, Denmark.

PHYSICO-CHEMICAL PROPERTY – OCTANOL/WATER PARTITION COEFFICIENT	
Test Substance	
Chemical Name	Tall oil fatty acids, low boiling
CAS #	65977-03-7
Remarks	This substance is also referred to as tall oil heads in the Final Data Summary for Tall Oil Fatty Acids and Related Substances.
Method	
Method/Guideline followed	Testing was conducted according to OECD Test Method 117, *"Partition Coefficient (n-Octanol/Water) High Performance Liquid*

	Chromatograph (HPLC) Method"
Test Type	Partition coefficient
GLP (Y/N)	Y
Year (Study Performed)	1993
Test conditions	Tall oil heads was dissolved in methanol and the solution was analyzed by HPLC with UV detection using a mobile phase of methanol:buffer (3:1) at pH 2 and pH 7.5. A mixture of seven materials with known log P_{ow} values was used for reference.
Results	At pH 2, the log P_{ow} values of nine components in tall oil heads were 4.4, 6.7, 6.9, 7.0, 7.2, 7.2, 7.4, 7.7, and 7.8. At pH 7.5, the log P_{ow} values of seven components in tall oil heads were 4.6, 6.5, 6.9, 6.9, 7.3, 7.4, and 8.0.
Data Quality	Reliable without restrictions – Klimisch Code 1a
Reference	Dybdahl, H.P. 1993. Determination of log Pow for single components in tall oil heads. GLP Study No. 408335/474. Water Quality Institute, Horsh□lm, Denmark.

PHYSICO-CHEMICAL PROPERTY – OCTANOL/WATER PARTITION COEFFICIENT	
Test Substance	
Chemical Name	Fatty acids, C16-C18 and C18 unsaturated, branched and linear
CAS #	68955-98-6
Remarks	This substance is also referred to as monomer acid in the Final Data Summary for Tall Oil Fatty Acids and Related Substances.
Method	
Method/Guideline followed	Testing was conducted according to Method A8 of Commission Directive 92/69/EEC
Test Type	Partition coefficient
GLP (Y/N)	N
Year (Study Performed)	1994
Test conditions	Not specified
Results	Fatty acids, C16 - C18 and C18 unsaturated, branched and linear had a partition coefficient of 7.93×10^4 at 25°C, or a Log_{10} P_{ow} of 4.90.
Data Quality	Reliable with restrictions – Klimisch Code 2a
Reference	Mullee, D.M. 1994. Determination of partition coefficient. Project ID No. 508/027. SafePharm Laboratories Ltd., Derby, England.

PHYSICO-CHEMICAL PROPERTY – OCTANOL/WATER PARTITION COEFFICIENT	
Test Substance	
Chemical Name	Octadecanoic acid, branched and linear
CAS #	68201-37-6
Remarks	This substance is also referred to as hydrogenated monomer acid in the Final Data Summary for Tall Oil Fatty Acids and Related Substances.
Method	
Method/Guideline followed	Testing was conducted according to OECD Test Method 117, *"Partition Coefficient (n-Octanol/Water) High Performance Liquid Chromatograph (HPLC) Method"*
Test Type	Partition coefficient
GLP (Y/N)	Y
Year (Study Performed)	2002
Test conditions	Octadecanoic acid, branched and linear and reference materials

	were dissolved in methanol and the solutions were analyzed in duplicate by HPLC with Refractive Index (RI) and Photodiode Array (PDA) detection using a mobile phase of 25:75 (v/v) Milli-Q water/methanol at pH 2. A mixture of seven materials with known log P_{ow} values was used for reference.
Results	At pH 2, octadecanoic acid, branched and linear had a partition coefficient range of 5.6 to 6.1.
Data Quality	Reliable without restrictions – Klimisch Code 1a
Reference	Lightbody, S.M., Fisher, K. and Dinwoodie, N.B. 2002. Determination of the Partition Coefficient of Fatty Acids and Fatty Acid Salts. Report No. 20976. Inveresk Research, Tranent, Scotland.

PHYSICO-CHEMICAL PROPERTY – OCTANOL/WATER PARTITION COEFFICIENT	
Test Substance	
Chemical Name	Fatty acids, tall oil, potassium salts
CAS #	61790-44-1
Method	
Method/Guideline followed	Testing was conducted according to OECD Test Method 117, *"Partition Coefficient (n-Octanol/Water) High Performance Liquid Chromatograph (HPLC) Method"*
Test Type	Partition coefficient
GLP (Y/N)	Y
Year (Study Performed)	2002
Test conditions	Fatty acids, tall oil, potassium salts and reference materials were dissolved in methanol and the solutions were analyzed in duplicate by HPLC with Refractive Index (RI) and Photodiode Array (PDA) detection using a mobile phase of 25:75 (v/v) Milli-Q water/methanol at pH 2. A mixture of seven materials with known log P_{ow} values was used for reference.
Results	At pH 2, fatty acids, tall oil, potassium salts had a partition coefficient range of 4.9 to 7.6.
Data Quality	Reliable without restrictions – Klimisch Code 1a
Reference	Lightbody, S.M., Fisher, K. and Dinwoodie, N.B. 2002. Determination of the Partition Coefficient of Fatty Acids and Fatty Acid Salts. Report No. 20976. Inveresk Research, Tranent, Scotland.

PHYSICO-CHEMICAL PROPERTY – OCTANOL/WATER PARTITION COEFFICIENT	
Test Substance	
Chemical Name	Fatty acids, tall oil, sodium salts
CAS #	61790-45-2
Method	
Method/Guideline followed	Testing was conducted according to OECD Test Method 117, *"Partition Coefficient (n-Octanol/Water) High Performance Liquid Chromatograph (HPLC) Method"*
Test Type	Partition coefficient
GLP (Y/N)	Y
Year (Study Performed)	2002
Test conditions	Fatty acids, tall oil, sodium salts and reference materials were dissolved in methanol and the solutions were analyzed in duplicate by HPLC with Refractive Index (RI) and Photodiode Array (PDA) detection using a mobile phase of 25:75 (v/v) Milli-Q water/methanol at pH 2. A mixture of seven materials with known log P_{ow} values was used for reference.

Results	At pH 2, fatty acids, tall oil, sodium salts had a partition coefficient range of 4.9 to 7.6.
Data Quality	Reliable without restrictions – Klimisch Code 1a
Reference	Lightbody, S.M., Fisher, K. and Dinwoodie, N.B. 2002. Determination of the Partition Coefficient of Fatty Acids and Fatty Acid Salts. Report No. 20976. Inveresk Research, Tranent, Scotland.

ENVIRONMENTAL FATE – BIODEGRADATION	
Test Substance	
Chemical Name	Tall oil fatty acid
CAS #	61790-12-3
Remarks	This substance is also referred to as TOFA in the Final Data Summary for Tall Oil Fatty Acids and Related Substances.
Method	
Method/Guideline followed	Testing was conducted according to OECD Test Method 301 D, *"Ready Biodegradability: Closed Bottle Test"*
Test Type (aerobic/anaerobic)	Aerobic
GLP (Y/N)	Y
Year (Study Performed)	1993
Contact time	28 days
Inoculum	Secondary effluent from Rungsted Treatment plant
Test conditions	Inoculum: Secondary effluent was collected from Rungsted Treatment plant. Concentration of test chemical: A stock solution of the test material (2 g/L) was prepared in demineralized water by ultra sonication for 5 minutes. Test Setup: Test medium was prepared by adding 1 mL each of four solutions (potassium phosphate, magnesium sulfate, calcium chloride, ferric chloride) to 1 liter of demineralized water, which was aerated to an initial oxygen concentration of 9 mg O_2/L and inoculated with 1 drop of secondary effluent per liter. The test article was added at 2 mg/L to a part of the inoculated test medium, equivalent to a chemical oxygen demand of 5.03 mg O_2/L. Sodium benzoate, the reference compound, was added at 2 mg/L to another part of the inoculated medium (to assess the activity of the inoculum), equivalent to a theoretical oxygen demand of 3.34 mg O_2/L. Both the test and reference articles (2 mg/L) were added to a third part of the inoculated medium (to assess possible inhibitory effects of the test article), at a theoretical oxygen demand of 8.37 mg O_2/L. Blank controls were prepared using the inoculated medium without test or reference materials. After the samples were prepared, the medium was transferred to calibrated respirometric bottles (BOD bottles), and placed in the dark at 20°C. The study was performed in triplicate. Sampling frequency: Samples were collected for BOD analysis on days 0, 7, 14, 21, and 28. Controls: Yes.

	Method of calculating oxygen demand: Oxygen demand was calculated as the difference between the measured oxygen concentrations at time t and the start of the test. Biological oxygen demand was calculated by subtracting the oxygen demand for the blank controls from the oxygen demand in the bottles containing test and reference compounds.
Results Degradation % after time	50% after 7 days and 56% after 28 days (test article); 63% after 7 days and 77% after 28 days (sodium benzoate)
Conclusions	The biological oxygen demand for tall oil fatty acid was 50 and 56% of the theoretical oxygen demand after 7 and 28 days, respectively. The rapid oxygen consumption in the first week and the total oxygen demand at the termination of the experiment indicate that the test material was dominated by readily biodegradable compounds. Tall oil fatty acid did not inhibit the respiratory activity of the inoculum.
Data Quality	Reliable without restrictions– Klimisch Code 1a
Reference	Madsen, T. 1993. Biodegradation of tall oil fatty acid. GLP Study No. 308067/472. Water Quality Institute, Horsh□lm, Denmark.

ENVIRONMENTAL FATE – BIODEGRADATION	
Test Substance	
Chemical Name	Tall oil fatty acid
CAS #	61790-12-3
Remarks	This substance is also referred to as TOFA in the Final Data Summary for Tall Oil Fatty Acids and Related Substances.
Method	
Method/Guideline followed	Testing was conducted according to OECD Test Method 301 F, *"Manometric respiratory test for biological degradation"*
Test Type (aerobic/anaerobic)	Aerobic
GLP (Y/N)	Y
Year (Study Performed)	1999
Contact time	28 days
Inoculum	Activated sludge from a municipal sewage treatment plant
Test conditions	Inoculum: Activated sludge from the municipal sewage treatment plant in Reutlingen was washed twice with tap water and centrifuged. Concentration of test chemical: A stock solution of the test material (101.5 mg/L) was prepared. Test Setup: Mineral medium was prepared by adding 10 mL of a potassium phosphate solution and 1 mL each of three other solutions (magnesium sulfate, calcium chloride, ferric chloride) to make a total volume of 1 liter in demineralized water. Six flasks were prepared: two of the test article in mineral medium with inoculum (24 mg/L); two of the mineral medium plus the inoculum (24 mg/L); one of the reference substance [sodium benzoate (98.5 mg/L)] with inoculum (24 mg/L); and one of the test article

	in water with sterilized medium. Sampling frequency: Samples were collected for analysis on days 14 and 28. Controls: Yes. Method of calculating oxygen demand: Biological oxygen demand was calculated by subtracting the oxygen demand for the blank controls from the oxygen demand in the flasks containing test and reference compounds.
Results	
Degradation % after time	84% after 28 days (test article); 97% after 28 days (sodium benzoate)
Conclusions	Eighty-four percent of tall oil fatty acid was biodegraded after 28 days indicating that the organic portion of the test material was readily biodegradable.
Data Quality	Reliable without restrictions– Klimisch Code 1a
Reference	Aniol, S. 1999. Biological degradation (Manometric respirometry test). STZ Project No. 03/99. Steinbeis-Transferzentrum Angewandte und Umwelt-Chemie, Reutungen.

ENVIRONMENTAL FATE – BIODEGRADATION	
Test Substance	
Chemical Name	Tall oil fatty acid
CAS #	61790-12-3
Remarks	This substance is also referred to as TOFA in the Final Data Summary for Tall Oil Fatty Acids and Related Substances.
Method	
Method/Guideline followed	Testing was conducted according to the CO_2 Evolution Test (Modified Sturm Test), EPA guideline number OPPTS 853.110, *"Ready Biodegradability"*
Test Type (aerobic/anaerobic)	Aerobic
GLP (Y/N)	N
Year (Study Performed)	1994
Contact time	29 days
Inoculum	Activated sludge from the Servern Trent water sewage treatment plant
Test conditions	Inoculum: Activated sludge microorganisms were obtained from the Servern Trent water sewage treatment plant at Belper, Derbyshire. A 1% inoculum was prepared. Concentration of test chemical: The test material was used at a concentration of 20 mg/L. Test Setup: Culture medium was prepared by adding 10 mL of a potassium phosphate solution and 1 mL each of three other solutions (magnesium sulfate, calcium chloride, ferric chloride) to a final volume of 1 liter in purified water. Twenty-four hours prior to study initiation, vessels were filled with 2400 mL of culture medium and 30 mL of inoculum and aerated over night. On day

	0 of the study, the test and reference material (sodium benzoate, 10 mg/L) were added and the total volume was increased to 3 liters. The following series of vessels was prepared: culture medium with inoculum; culture medium with inoculum and sodium benzoate; and culture medium with inoculum and test material. The CO_2 absorption bottles were connected to the outlet and were sealed. CO_2-free air was bubbled through the solution and they were stirred continuously. All experiments were performed in the dark at 20 to 22°C. Sampling frequency: Samples (2 mL) were collected from the first CO_2 absorber vessel on days 0, 1, 2, 3, 6, 8, 10, 14, 16, 18, 20, 22, 24, 27, 28, and 29, and from the second absorber on days 0 and 29. Controls: Yes. Analysis: Samples from the CO_2 absorbers were injected into the inorganic carbon channel of the total carbon analyzer for direct analysis of evolved CO_2. The analyses were conducted in triplicate.
Degradation % after time	74% after 28 days (test article); 80% after 28 days (sodium benzoate)
Conclusions	The test article was degraded 74% after 28 days and sodium benzoate was degraded 80% after 28 days. Under the conditions of the OECD guidelines, the test article cannot be considered to be readily biodegradable.
Data Quality	Reliable without restrictions– Klimisch Code 1b
Reference	Sewell, I.G. 1994. Assessment of ready biodegradability using the CO_2 evolution test (modified Sturm test). Project No. 508/28. SafePharm Laboratories Ltd., Derby, England.

ENVIRONMENTAL FATE – BIODEGRADATION	
Test Substance	
Chemical Name	Tall oil fatty acids, low boiling
CAS #	65997-03-2
Remarks	This substance is also referred to as tall oil heads in the Final Data Summary for Tall Oil Fatty Acids and Related Substances.
Method	
Method/Guideline followed	Testing was conducted according to OECD Test Method 301 D, *"Ready Biodegradability: Closed Bottle Test"*
Test Type (aerobic/anaerobic)	Aerobic
GLP (Y/N)	Y
Year (Study Performed)	1993
Contact time	28 days
Inoculum	Secondary effluent from Rungsted Treatment plant
Test conditions	Inoculum: Secondary effluent was collected from Rungsted Treatment plant. Concentration of test chemical: A stock solution of the test material (2 g/L) was prepared in demineralized water by ultra sonication for 5 minutes.

	Test Setup: Test medium was prepared by adding 1 mL each of four solutions (potassium phosphate, magnesium sulfate, calcium chloride, ferric chloride) to 1 liter of demineralized water, which was aerated to an initial oxygen concentration of 9 mg O_2/L and inoculated with 1 drop of secondary effluent per liter. The test article was added at 2.4 mg/L to a part of the inoculated test medium, equivalent to a chemical oxygen demand of 4.94 mg O_2/L. Sodium benzoate, the reference compound, was added at 2 mg/L to another part of the inoculated medium (to assess the activity of the inoculum), equivalent to a theoretical oxygen demand of 3.34 mg O_2/L. Both the test and reference articles were added to a third part of the inoculated medium (to assess possible inhibitory effects of the test article), at a theoretical oxygen demand of 8.28 mg O_2/L. Blank controls were prepared using the inoculated medium without test or reference materials. After the samples were prepared, the medium was transferred to calibrated respirometric bottles (BOD bottles), and placed in the dark at 20°C. The study was performed in triplicate. Sampling frequency: Samples were collected for BOD analysis on days 0, 7, 14, 21, and 28. Controls: Yes. Method of calculating oxygen demand: Oxygen demand was calculated as the difference between the measured oxygen concentrations at time t and the start of the test. Biological oxygen demand was calculated by subtracting the oxygen demand for the blank controls from the oxygen demand in the bottles containing test and reference compounds.
Results Degradation % over time	33% after 7 days and 41% after 28 days (test article); 63% after 7 days and 77% after 28 days (sodium benzoate)
Conclusions	The biological oxygen demand for tall oil heads was 33 and 41% of the theoretical oxygen demand after 7 and 28 days, respectively. These results indicate that the test material contains readily biodegradable and recalcitrant compounds. Tall oil heads did not inhibit the respiratory activity of the inoculum.
Data Quality	Reliable without restrictions– Klimisch Code 1a
Reference	Madsen, T. 1993. Biodegradation of tall oil heads. GLP Study No. 308067/474. Water Quality Institute, Horsh□lm, Denmark.

ENVIRONMENTAL FATE – BIODEGRADATION	
Test Substance	
Chemical Name	Fatty acids, C16 - C18 and C18 unsaturated, branched and linear
CAS #	68955-98-6
Remarks	This substance is also referred to as monomer acid in the Final Data Summary for Tall Oil Fatty Acids and Related Substances.
Method	

Method/Guideline followed	Testing was conducted according to the CO_2 Evolution Test (Modified Sturm Test), EPA guideline number OPPTS 853.110, *"Ready Biodegradability"*
Test Type (aerobic/anaerobic)	Aerobic
GLP (Y/N)	N
Year (Study Performed)	1994
Contact time	29 days
Inoculum	Activated sludge from the Severn Trent water sewage treatment plant
Test conditions	Inoculum: Activated sludge microorganisms were obtained from the Severn Trent water sewage treatment plant at Belper, Derbyshire. A 1% inoculum was prepared. Concentration of test chemical: The test material was used at a concentration of 20 mg/L. Test Setup: Culture medium was prepared by adding 10 mL of a potassium phosphate solution and 1 mL each of three other solutions (magnesium sulfate, calcium chloride, ferric chloride) to a final volume of 1 liter in purified water. Twenty-four hours prior to study initiation, vessels were filled with 2400 mL of culture medium and 30 mL of inoculum and aerated over night. On day 0 of the study, the test and reference material (sodium benzoate, 10 mg/L) were added and the total volume was increased to 3 liters. The following series of vessels was prepared: culture medium with inoculum; culture medium with inoculum and sodium benzoate; and culture medium with inoculum and test material. The CO_2 absorption bottles were connected to the outlet and were sealed. CO_2-free air was bubbled through the solution and they were stirred continuously. All experiments were performed in the dark at 21 to 22°C. Sampling frequency: Samples (2 mL) were collected from the first CO_2 absorber vessel on days 0, 1, 2, 3, 6, 8, 10, 12, 14, 16, 20, 22, 24, 27, 28, and 29, and from the second absorber on days 0 and 29. Controls: Yes. Analysis: Samples from the CO_2 absorbers were injected into the inorganic carbon channel of the total carbon analyzer for direct analysis of evolved CO_2. The analyses were conducted in triplicate.
Results Degradation % after time	67% after 28 days (test article); 87% after 28 days (sodium benzoate)
Conclusions	The test article was degraded 67% after 28 days. Under the conditions of the OECD guidelines, it cannot be considered to be readily biodegradable.
Data Quality	Reliable without restrictions– Klimisch Code 1b
Reference	Sewell, I.G. 1994. Assessment of ready biodegradability using the CO2 evolution test (modified Sturm test). Project No. 508/23. SafePharm Laboratories Ltd., Derby, England.

ENVIRONMENTAL FATE – BIODEGRADATION	
Test Substance	
Chemical Name	Octadecanoic acid, branched and linear
CAS #	68201-37-6
Remarks	This substance is also referred to as hydrogenated monomer acid in the Final Data Summary for Tall Oil Fatty Acids and Related Substances.
Method	
Method/Guideline followed	Testing was conducted according to OECD (1992) 301B Modified Sturm Test
Test Type (aerobic/anaerobic)	Aerobic
GLP (Y/N)	Y
Year (Study Performed)	2002
Contact time	28 days
Inoculum	Activated sludge from the Haddington Municipal Sewage Treatment Works
Test conditions	Inoculum: Activated sludge microorganisms were obtained from the Haddington Municipal Sewage Treatment Works. The solids content of the sludge was 3.2 g/l. Concentration of test chemical: The test material was used at a concentration of 20 mg DOC/L. Based on the percentage carbon content, a target weight of 53.6 mg of test material was weighed for direct addition to each appropriate bioreactor. Test Setup: Each test item bioreactor contained 1980 ml of mineral media, 20 ml of microbial inoculum and 54 mg of test item. The reference bioreactor contained 1911 ml of mineral media, 20 ml of microbial inoculum and 69 ml of reference material (sodium benzoate) stock. The control bioreactors each contained 1980 ml of mineral media and 20 ml of microbial inoculum. The toxicity control bioreactor contained 1911 ml of mineral media, 20 ml of microbial inoculum, 53.9 mg of test item and 69 ml reference material stock. Each bioreactor was connected to three traps, each trap containing 100 ml of 0.0125 M $Ba(OH)_2$. At trap collection, the trap closes to the bioreactor was taken for titration, the two remaining traps were moved closer to the bioreactor and a fresh trap was placed third in line from the bioreactor. Trap changes were conducted on days 1, 4, 6, 8, 11, 15, 18, 21, 26, and 29. Each sampled trap was titrated with a few drops of phenolphthalein indicator against 0.05M HCl. The pH was determined in each bioreactor on days 0, 28 and 29; if necessary, the pH on day 0 was adjusted to 7.2-7.8. Calculation of Results: The weight of CO_2 evolved was calculated from the titre. The actual titre for each batch of $Ba(OH)_2$ was used as the background titre. The mean titre for the test, reference and control vessels was calculated according to the following equation: Weight CO_2 produced (mg) = 1.1 x (background titre – ml HCl

	titrated) The net CO_2 production was then calculated by subtracting the control mean CO_2 production from the test and reference material mean CO_2 production values. The percentage biodegradation was calculated by comparing actual CO_2 evolved in test and reference vessels with the theoretical CO_2 evolution. For the test item this was calculated using the DOC addition rate: $\% \text{ degradation} = \frac{\text{Mg } CO_2 \text{ produced}}{\text{mg DOC added} \times 3.67^{*}} \times 100$ * = where 3.67 is the conversion factor (44/12) for carbon to CO_2
Results Degradation % after time	46.72% after 28 days (test article); 68.39% after 28 days (sodium benzoate)
Conclusions	The test article was degraded 47% after 28 days. Under the conditions of the OECD guidelines, it cannot be considered to be readily biodegradable.
Data Quality	Reliable without restrictions– Klimisch Code 1a
Reference	Kelly, C.R. 2002. Octadecanoic acid, branched and linear, CAS No. 68201-37-6 Determination of Ready Biodegradability by the Modified Sturm Test. Report No. 21136. Inveresk Research, Tranet, Scotland.

ENVIRONMENTAL FATE – BIODEGRADATION	
Test Substance	
Chemical Name	Fatty acids, tall oil, sodium salt
CAS #	61790-45-2
Method	
Method/Guideline followed	Testing was conducted according to OECD (1992) 302B Modified Zahn-Wellens Test
Test Type (aerobic/anaerobic)	Aerobic
GLP (Y/N)	Y
Year (Study Performed)	2002
Contact time	28 days
Inoculum	Activated sludge from the Haddington Municipal Sewage Treatment Works
Test conditions	Inoculum: Activated sludge microorganisms were obtained from the Haddington Municipal Sewage Treatment Works. The solids content of the sludge was 4.0 g/l. Concentration of test chemical: The test material was used at a concentration of 200 mg DOC/L equivalent to 4480 mg of fatty acid, tall oil, sodium salt per 2.5 liter bioreactor based on percentabe carbon content. To prepare the reference material (aniline) 8.09 ml was added to 1000 ml DI water and sonicated for *ca* 30 min. to aid dissolution; from this stock 125 ml aliquots were added to each appropriate bioreactor.

	Test Setup: The activated sludge was introduced to the test system at a ratio of 2.5:1 sludge solids/l to test item DOC/l which required the addition of 250 ml of 4 g/l sludge to each bioreactor. A total of six bioreactors were used. Each bioreactor had a final volume of 2000 ml; the control bioreactors each contained 250 ml sludge and 1750 ml of mineral medium; the reference bioreactor contained 250 ml sludge, 125 ml of aniline stock solution and 1625 of mineral medium; the test item bioreactors each contained 250 ml sludge, the appropriate weight of test item and 1750 ml of mineral medium; the toxicity control bioreactor contained 250 ml sludge, the appropriate weight of test item, 125 ml aniline stock and 1625 ml mineral medium. The test was conducted over 28 days. DOC measurements were conducted on duplicate samples 3 h after test initiation, and on Days 14 and 28. Sampling Procedure: Prior to each sampling point the liquid in each vessel was replenished to its starting level. The pH and dissolved oxygen concentration were recorded. If necessary the pH was adjusted to 6.5-8.0 using H_2SO_4 as appropriate. A *ca* 25 ml sample was extracted from each vessel using a syringe and allowed to settle after which it was passed through a 0.45um filter for DOC analysis. Determination of DOC, total organic carbon (TOC), total carbon (TC) and inorganic carbon (IC) were determined. Calculation of Results: All measurements were conducted on duplicate samples. Dissolved organic carbon (DOC) values were calculated as follows: $DOC = TC - IC$ The percentage degradation (Dt) at each timepoint was calculated using mean DOC measurements from the duplicate samples, using the following equation: $Dt = \left(1 - \frac{Ct - Cb}{Ca - Cba}\right) \times 100$ Where: Ct = mean DOC concentration in test/reference at time t Cb = mean DOC concentration in controls at time t Ca = mean DOC concentration in test/reference at 3 h ± 0.5 h Cba = mean DOC concentration in controls at 3 h ± 0.5 h
Results Degradation % after time	The test item reached 73.8 % degradation by Day 14 and 98.4 % by Day 28; the material reached 97% degradation by Day 14.
Conclusions	The test article was degraded 98% after 28 days under the conditions of the test.
Data Quality	Reliable without restrictions– Klimisch Code 1a
Reference	Kelly, C.R. 2002. Fatty acid, tall oil, sodium salt, CAS No. 61790-45-2 Determination of Inherent Biodegradability by the

	Modified Zahn-Wellens Test. Report No. 21485. Inveresk Research, Tranet, Scotland.

ENVIRONMENTAL FATE – BIODEGRADATION	
Test Substance	
Chemical Name	Tall oil fatty acids, potassium salt
CAS #	61790-44-1
Method	
Method/Guideline followed	Testing was conducted according to a modified OECD test for ready biodegradability, EPA guideline number OPPTS 853.110, *"Ready Biodegradability"*
Test Type (aerobic/anaerobic)	Aerobic
GLP (Y/N)	Y
Year (Study Performed)	1991
Contact time	28 days
Inoculum	Activated sludge from Bergen County sewage treatment plant
Test conditions	Inoculum: Activated sludge from Bergen County sewage treatment plant was mixed with soil extract and surface water to prepare the inoculum. Concentration of test chemical: The test article was tested at a concentration of 20 to 25 ppm. Test Setup: OECD test medium was used. Aniline was the reference material and was tested at a concentration of 20 to 25 ppm. The experiments were performed in the dark at 20 to 25°C. Sampling frequency: Samples were collected for analysis on days 0, 7, 14, 21, and 28. Controls: Yes. Method of calculating degradation: The mean initial concentration of soluble organic carbon (SOC) in the controls is subtracted from the initial concentration in the test sample. From this is subtracted, the mean initial concentration of SOC in the test and control samples at time t. This value is divided by the mean initial concentration of SOC in the controls subtracted from the initial concentration in the test sample.
Results	
Degradation % after time	79% after 28 days (test article); 97% after 28 days (aniline)
Conclusions	The test material degraded 79% and is considered to be readily biodegradable as defined by OECD.
Data Quality	Reliable without restrictions– Klimisch Code 1b
Reference	Drozdowki, D. 1991. Modified OECD test for ready biodegradability of [product name deleted] tall oil fatty acid potassium salt. Report No. 063383-1. United States Testing Company, Inc., Hoboken, New Jersey.

ECOTOXICITY – ACUTE TOXICITY TO FISH	
Test substance	
Chemical Name	Tall oil fatty acid
CAS #	61790-12-3
Remarks	This substance is also referred to as TOFA in the Final Data Summary for Tall Oil Fatty Acids and Related Substances.
Method	
Method/Guideline followed	OECD Test Method 203, *"Testing of Chemicals, Fish Acute Toxicity Test"* and following procedures in OECD (2000) Guidance Document No. 23 on Testing Difficult Substances.
Year	2002
GLP (Y/N)	Y
System of testing	Fathead minnows (*Pimephales promelas)* under static conditions.
Concentration	0, 1, 10, 100 and 1000 mg/l
Results	The 96 hr LL_{50} was > 1000 mg/l the highest loading rate tested. The No Observed Effect Loading Rate ($NOEL_r$) was 1000 mg/l.
Detailed Summary	Tall oil fatty acid (TOFA) was tested in fathead minnows under static conditions to determine the acute toxicity. Water accommodated fractions (WAF) were prepared using the same conditions as those used to determine the water solubility of this substance. Appropriate weights of TOFA were added to a stirring medium in glass vessels which were sealed to avoid loss of volatile fractions. Using magnetic stirrers, the stirring speed was adjusted to give a stirring vortex 5-10% of the water column. After a stirring period of approximately 48 hr. the test solutions were allowed to settle for ca hour. The WAF was then removed via a glass siphon taking care not to remove undissolved material at the top of bottom of the water column. The test organisms were exposed to this WAF. This procedure was adopted to maximize the solubility of the test item under specific test exposure conditions, but to reduce exposure to the test organisms to insoluble fractions. A control medium without the addition of the test item was stirred and extracted in an identical ways as the treated media. The effects of both filtering and adjusting pH were investigated in a range finding test using the highest loading rate (i.e., 1000 mg/l). Because no mortality or other effects were observed in the range finding tests, a definitive-limit test was conducted at the maximum loading rate of 1000 mg/l. The 96 hr LL_{50} was > 1000 mg/l, the highest loading rate tested. The No Observed Effect Loading Rate ($NOEL_r$) was 1000 mg/l.
Data Quality	Valid without restriction – Klimisch Code 1a
Reference	Kelly, C. 2002. Fatty acids, tall oil, CAS No. 61790-12-3 Determination of Acute Toxicity (LL_{50}) to Fathead Minnows (96 h, Static). Report No. 20621. Inveresk Research, Tranent, Scotland.

ECOTOXICITY – ACUTE TOXICITY TO FISH	
Test substance	
Chemical Name	Fatty acids, C16-C18 and C18 unsaturated, branched and linear
CAS #	68955-98-6
Remarks	This substance is also referred to as monomer acid in the Final Data Summary for Tall Oil Fatty Acids and Related Substances.

Method	
Method/Guideline followed	OECD Test Method 203, *"Testing of Chemicals, Fish Acute Toxicity Test."*
Year	1994
GLP (Y/N)	Y
System of testing	Golden orfe (*Leuciscus idus.*) under static conditions.
Concentration	1000 mg/l
Results	The 96 hr LL_{50} was > 1000 mg/l the highest loading rate tested. The No Observed Effect Concentration Loading Rate ($NOEC_r$) was 1000 mg/l.
Detailed Summary	Fatty acid, C16 and C18 and C18 unsaturated, branched and linear was tested in golden orfe under static conditions to determine the acute toxicity. A range finding test was conducted during which no mortality was observed at a concentration of 1000 mg/l. For the definitive test, water accommodated fractions (WAF) were prepared by placing 1000 mg/l of test material on the surface of dechlorinated tap water. This was stirred using a magnetic stirrer for 24 hr prior to the test with care taken to avoid the formation of a vortex during mixing. After 24 hr. the mixture was allowed to stand for 1 hr. prior to removing the aqueous phase (i.e., WAF) by a siphon to glass exposure vessels for testing. The test organisms were exposed to this WAF. Because no mortality or other effects were observed in the range finding tests, a definitive-limit test was conducted at the maximum loading rate of 1000 mg/l. There were no mortalities or other adverse reactions in 20 fish exposed to a 1000 mg/l WAF loading rate for a period of 96 hr. The 96 hr LL_{50} was > 1000 mg/l, the highest loading rate tested. The No Observed Effect Loading Rate ($NOEL_r$) was 1000 mg/l.
Data Quality	Valid without restriction – Klimisch Code 1a
Reference	Sewell, I.G. 1994. [Fatty acid, C16 and C18 and C18 unsaturated, branched and linear] Acute Toxicity to Golden Orfe. SafePharm Laboratories Ltd. Durham, England.

ECOTOXICITY – ACUTE TOXICITY TO FISH	
Test substance	
Chemical Name	Fatty acids, C16-C18 and C18 unsaturated, branched and linear, calcium salt
CAS #	Not assigned
Remarks	This substance is also referred to as monomer acid calcium salt in the Final Data Summary for Tall Oil Fatty Acids and Related Substances.
Method	
Method/Guideline followed	OECD Test Method 203, *"Testing of Chemicals, Fish Acute Toxicity Test."*
Year	2002
GLP (Y/N)	Y
System of testing	Rainbow trout (*Oncorhynchus mykiss.*) under static conditions.
Concentration	100 mg/l
Results	The 96 hr LL_{50} was > 100 mg/l the highest loading rate tested. The No Observed Effect Loading Rate ($NOEL_r$) was 100 mg/l.
Detailed Summary	Monomer acid, calcium salt was tested in rainbow trout under

	static conditions to determine the acute toxicity. A range finding test was conducted during which no mortality was observed at a concentration of 100 mg/l. It was considered unnecessary and unrealistic to test at loading rates in excess of 100 mg/l. For the definitive test, water accommodated fractions (WAF) were prepared by placing 2100 mg of test material on the surface of 21L of dechlorinated tap water to yield the 100 mg/l loading rate. This was stirred using a magnetic stirrer for 23 hr prior to the test with care taken to ensure that the vortex formed was only a dimple on the water surface. After 23 hr. the mixture was allowed to stand for 1 hr. prior to removing the aqueous phase (i.e., WAF) by a siphon to glass exposure vessels for testing. Microscopic inspection of the WAF showed no micro-dispersions or undissolved test material. The test organisms were exposed to this WAF. Because no mortality or other effects were observed in the range finding tests, a definitive-limit test was conducted at the maximum loading rate of 100 mg/l. There were no mortalities or other adverse reactions in 20 fish exposed to a 100 mg/l WAF loading rate for a period of 96 hr. The 96 hr LL_{50} was > 100 mg/l, the highest loading rate tested. The No Observed Effect Loading Rate ($NOEL_r$) was 100 mg/l.
Data Quality	Valid without restriction – Klimisch Code 1a
Reference	Shacklady, L.G. and Mullee, D.M. 2002. [Monomer acid, calcium salt] Acute Toxicity to Rainbow Trout (*Oncorhynchus* mykiss). SPL Proj. No. 1078/087. SafePharm Laboratories Ltd. Durham, U.K.

ECOTOXICITY – ACUTE TOXICITY TO DAPHNIA	
Test substance	
Chemical Name	Tall oil fatty acid
CAS #	61790-12-3
Remarks	This substance is also referred to as TOFA in the Final Data Summary for Tall Oil Fatty Acids and Related Substances.
Method	
Method/Guideline followed	OECD Test Method 202, Part 1 *"Testing of Chemicals, Daphnia sp. Acute Immobilization Test"* and following procedures in OECD (2000) Guidance Document No. 23 on Testing Difficult Substances.
Year	2002
GLP (Y/N)	Y
System of testing	*Daphnia magna* (water fleas) under static conditions.
Concentration	0, 1, 10, 100 and 1000 mg/l
Results	The 48 hr EL_{50} was > 1000 mg/l the highest loading rate tested. The No Observed Effect Loading Rate ($NOEL_r$) was 1000 mg/l.
Detailed Summary	Tall oil fatty acid (TOFA) was tested in daphnia under static conditions to determine the acute toxicity. Water accommodated fractions (WAF) were prepared using the same conditions as those used to determine the water solubility of this substance. Appropriate weights of TOFA were added to a stirring medium in glass vessels which were sealed to avoid loss of volatile fractions. Using magnetic stirrers, the stirring speed was adjusted to give a stirring vortex 5-10% of the water column. After a stirring period of approximately 48 hr. the test solutions

	were allowed to settle for ca hour. The WAF was then removed via a glass siphon taking care not to remove undissolved material at the top of bottom of the water column. The test organisms were exposed to this WAF. This procedure was adopted to maximize the solubility of the test item under specific test exposure conditions, but to reduce exposure to the test organisms to insoluble fractions. A control medium without the addition of the test item was stirred and extracted in an identical ways as the treated media. The effects of both filtering and adjusting pH were investigated in a range finding test. Because no mortality or other effects were observed in the range finding tests, a definitive-limit test was conducted at the maximum loading rate of 1000 mg/l. The 48 hr EL_{50} was > 1000 mg/l, the highest loading rate tested. The No Observed Effect Loading Rate ($NOEL_r$) was 1000 mg/l.
Data Quality	Valid without restriction – Klimisch Code 1a
Reference	Kelly, C. 2002. Fatty acids, tall oil, CAS No. 61790-12-3 Determination of Acute Toxicity (EL_{50}) to Daphnia (48 h, Static). Report No. 20468. Inveresk Research, Tranent, Scotland.

ECOTOXICITY – ACUTE TOXICITY TO DAPHNIA	
Test substance	
Chemical Name	Fatty acids, C16-C18 and C18 unsaturated, branched and linear
CAS #	68955-98-6
Remarks	This substance is also referred to as monomer acid in the Final Data Summary for Tall Oil Fatty Acids and Related Substances.
Method	
Method/Guideline followed	OECD Test Method 202, Part 1 *"Testing of Chemicals, Daphnia sp. Acute Immobilization Test"*
Year	1994
GLP (Y/N)	Y
System of testing	Daphnia (*Daphnia magna.)* under static conditions.
Concentration	1000 mg/l
Results	The 48 hr Effective Loading Rate (ELR_{50}) was > 1000 mg/l the highest loading rate tested. The No Observed Effect Loading Rate ($NOEL_r$) at both 24 and 48 hr. was 1000 mg/l.
Detailed Summary	Fatty acid, C16 and C18 was tested in daphnia under static conditions to determine the acute toxicity. A range finding test was conducted during which no mortality was observed at a concentration (i.e., loading rate) of 1000 mg/l. For the definitive test, water accommodated fractions (WAF) were prepared by placing 1000 mg/l of test material on the surface of appropriate daphnia media. This was stirred using a magnetic stirrer for 24 hr prior to the test with care taken to avoid the formation of a vortex during mixing. After 24 hr. the mixture was allowed to stand for 1 hr. prior to removing the aqueous phase (i.e., WAF) by a siphon to glass exposure vessels for testing. The test organisms were exposed to this WAF. Because no mortality or other effects were observed in the range finding tests, a definitive-limit test was conducted at the maximum loading rate of 1000 mg/l. There were no immobilized daphnia or other adverse reactions in 40 daphnids exposed to a 1000 mg/l WAF loading rate for a period of 48 hr. The 48 hr Effective Loading Rate (ELR_{50}) was > 1000

	mg/l the highest loading rate tested. The No Observed Effect Loading Rate ($NOEL_r$) at both 24 and 48 hr. was 1000 mg/l.
Data Quality	Valid without restriction – Klimisch Code 1a
Reference	Sewell, I.G. 1994. [Fatty acid, C16 and C18] Acute Toxicity to Daphnia Magna. SafePharm Laboratories Ltd. Durham, England.

ECOTOXICITY – ACUTE TOXICITY TO DAPHNIA	
Test substance	
Chemical Name	Fatty acids, C16-C18 and C18 unsaturated, branched and linear, calcium salt
CAS #	Not assigned
Remarks	This substance is also referred to as monomer acid calcium salt in the Final Data Summary for Tall Oil Fatty Acids and Related Substances.
Method	
Method/Guideline followed	OECD Test Method 202, Part 1 *"Testing of Chemicals, Daphnia sp. Acute Immobilization Test"*
Year	2002
GLP (Y/N)	Y
System of testing	Daphnia (*Daphnia* magna) under static conditions.
Concentration	100 mg/l
Results	The 48 hr EL_{50} was > 100 mg/l the highest loading rate tested. The No Observed Effect Loading Rate ($NOEL_r$) was 100 mg/l.
Detailed Summary	Monomer acid, calcium salt was tested in daphnia under static conditions to determine the acute toxicity. A range finding test was conducted during which no mortality was observed at a concentration of 100 mg/l. It was considered unnecessary and unrealistic to test at loading rates in excess of 100 mg/l. For the definitive test, water accommodated fractions (WAF) were prepared by placing 1000 mg of test material on the surface of 10L of daphnia media to yield the 100 mg/l loading rate. This was stirred using a magnetic stirrer for 23 hr prior to the test with care taken to ensure that the vortex formed was only a dimple on the water surface. After 23 hr. the mixture was allowed to stand for 1 hr. prior to removing the aqueous phase (i.e., WAF) by a siphon to glass exposure vessels for testing. Microscopic inspection of the WAF showed no micro-dispersions or undissolved test material. The test organisms were exposed to this WAF. Because no mortality or other effects were observed in the range finding tests, a definitive-limit test was conducted at the maximum loading rate of 100 mg/l. There were no mortalities or other adverse reactions in 40 daphnia exposed to a 100 mg/l WAF loading rate for a period of 48 hr. The 48 hr EL_{50} was > 100 mg/l, the highest loading rate tested. The No Observed Effect Loading Rate ($NOEL_r$) was 100 mg/l.
Data Quality	Valid without restriction – Klimisch Code 1a
Reference	Shacklady, L.G. and Mullee, D.M. 2002. [Monomer acid, calcium salt] Acute Toxicity to *Daphnia Magna* SPL Proj. No. 1078/088. SafePharm Laboratories Ltd. Durham, U.K.

ECOTOXICITY – ALGA, GROWTH INHIBITION	
Test substance	
Chemical Name	Tall oil fatty acid
CAS #	61790-12-3
Remarks	This substance is also referred to as TOFA in the Final Data Summary for Tall Oil Fatty Acids and Related Substances.
Method	
Method/Guideline followed	OECD Test Method 201, *"Testing of Chemicals, Alga, Growrh Inhibition Test"* and following procedures in OECD (2000) Guidance Document No. 23 on Testing Difficult Substances.
Year	2002
GLP (Y/N)	Y
System of testing	Green alga (*Selenastrum capriconutum)* growth inhibition.
Concentration	0, 125, 250, 500 and 1000 mg/l
Results	The 72 hr EL_{50} for area under growth curve (AUC) was 854.90 mg/l with a corresponding No Observed Effect Loading Rate ($NOEL_r$) of 500 mg/l. The 72 hr. EL_{50} based on Average Specific Growth Rate was > 1000 mg/l with a corresponding $NOEL_r$ of 500 mg/l. at 0-48 hr and 750 mg/l at 0-72 hr. indicating some inhibition (<50%) compared to the control.
Detailed Summary	Tall oil fatty acid (TOFA) was tested in alga to determine the median effective loading (EL_{50}) for growth inhibition. Water accommodated fractions (WAF) were prepared using the same conditions as those used to determine the water solubility of this substance. Appropriate weights of TOFA were added to a stirring medium in glass vessels which were sealed to avoid loss of volatile fractions. Using magnetic stirrers, the stirring speed was adjusted to give a stirring vortex 5-10% of the water column. After a stirring period of approximately 48 hr. the test solutions were allowed to settle for ca hour. The WAF was then removed via a glass siphon taking care not to remove undissolved material at the top of bottom of the water column. The test organisms were exposed to this WAF. This procedure was adopted to maximize the solubility of the test item under specific test exposure conditions, but to reduce exposure to the test organisms to insoluble fractions. A control medium without the addition of the test item was stirred and extracted in an identical ways as the treated media. The effects of both filtering and adjusting pH were investigated in a range finding test at the highest loading rate. In the range finding test there was a 29% inhibitioin of growth at 1000 mg/l; after 72 hr. exposure cell numbers in all test solutions < 100 mg/l were higher than the standard controls. Based on the results of the range-finding test a definitive test was conducted at loading rates of 0, 125, 250, 500, 750 and 1000 mg/l. This test was conducted using an unfiltered WAF with no pH adjustment. The 72 hr EL_{50} for area under growth curve (AUC) was 854.90 mg/l with a corresponding No Observed Effect Loading Rate ($NOEL_r$) of 500 mg/l. The 72 hr. EL_{50} based on Average Specific Growth Rate was > 1000 mg/l with a corresponding $NOEL_r$ of 500 mg/l. at 0-48 hr and 750 mg/l at 0-72 hr. indicating some inhibition (<50%) compared to the control.

Data Quality	Valid without restriction – Klimisch Code 1a
Reference	Kelly, C. 2002. Fatty acids, tall oil, CAS No. 61790-12-3 Alga, Growth Inhibition Test (72 h, EL_{50}). Report No. 20706. Inveresk Research, Tranent, Scotland.

ECOTOXICITY – ALGA, GROWTH INHIBITION	
Test substance	
Chemical Name	Fatty acids, C16-C18 and C18 unsaturated, branched and linear
CAS #	68955-98-6
Remarks	This substance is also referred to as monomer acid in the Final Data Summary for Tall Oil Fatty Acids and Related Substances.
Method	
Method/Guideline followed	OECD Test Method 201, *"Testing of Chemicals, Alga, Growrh Inhibition Test"*
Year	1994
GLP (Y/N)	Y
System of testing	Alga (*Scenedesmus subspicatus)* under static conditions.
Concentration	1000 mg/l
Results	The 72 hr Effective Loading Rate that reduced biomass by 50% (E_bLR_{50}) was > 1000 mg/l WAF loading rate and the 24 hr Effective Loading Rate that reduced specific growth rate by 50% (E_rLR_{50}) was > 1000 mg/l WAF loading rate.
Detailed Summary	Fatty acid, C16 and C18 was tested in alga under static conditions to determine the extent of growth inhibition. A water accommodated fraction (WAF) was prepared by placing 2000 mg/l of test material on the surface of alga culture medium. This was stirred using a magnetic stirrer for 24 hr prior to the test with care taken to avoid the formation of a vortex during mixing. After 24 hr. the mixture was allowed to stand for 1 hr. prior to removing the aqueous phase (i.e., WAF) for testing. This 2000 mg/l WAF loading rate was diluted 50:50 with algal suspension to give a 1000 mg/l WAF loading rate. The test organisms were exposed to this WAF; six replicates were used. Samples were taken at 0, 24, 48 and 72 hrs. Cell densities of control and test cultures at 0 and 72 hrs. were determined by direct counting with a haemocytometer. Neither the growth nor the biomass of alga were affected by the presence of the test compound over the 72 hr. exposure period. The 72 hr Effective Loading Rate that reduced biomass by 50% (E_bLR_{50}) was > 1000 mg/l WAF loading rate and the 24 hr Effective Loading Rate that reduced specific growth rate by 50% (E_rLR_{50}) was > 1000 mg/l WAF loading rate.
Data Quality	Valid without restriction – Klimisch Code 1a
Reference	Sewell, I.G. 1994. Assessment of the Algistatic Effect of [Fatty acid, C16 and C18]. SafePharm Laboratories Ltd. Durham, England.

ACUTE TOXICITY – ORAL	
Test substance	
Chemical Name	Tall oil fatty acid
CAS #	61790-12-3
Remarks	This substance is also referred to as TOFA in the Final Data

	Summary for Tall Oil Fatty Acids and Related Substances.
Method	
Method/Guideline followed	Test procedure was consistent with OECD Test Method 401, *"Acute Oral Toxicity"*
GLP (Y/N)	Y
Year (Study Performed)	1983
Species	Rat
Strain	Sprague-Dawley
Route of administration	Oral
Dose levels	10,000 mg/kg
Sex and number/group	5 male and 5 female rats
Frequency of treatment	Single oral gavage
Duration of test	14 day observation post-treatment
Control group (Y/N)	N
Result	
Acute Oral LD_{50}	>10,000 mg/kg
Detailed Summary	Sprague-Dawley rats (n = 5/sex) received a single oral (gavage) dose of 10,000 mg/kg of fatty acid, tall oil (CAS #61790-12-3) and were observed for 14 days. Parameters evaluated included clinical signs, mortality, body weight, and gross pathology. None of the animals died. One hour post-dosing, piloerection was observed in one male and abnormal stance was observed in one male and one female. By four hours, these effects had resolved. No body weight effects were observed. Gross necropsy revealed no treatment-related effects. The acute oral LD_{50} was greater than 10,000 mg/kg.
Data Quality	Valid without restriction – Klimisch Code 1a
Reference	Mallory, V.T. 1983. Acute oral toxicity study in rats: fatty acid [product name deleted]. Study No. PH 402-AC-009-83. Pharmakon Research International, Inc., Waverly, Pennsylvania.

ACUTE TOXICITY – ORAL	
Test substance	
Chemical Name	Fatty acids, C16-C18 and C18 unsaturated, branched and linear, sodium salt
CAS #	Not assigned
Remarks	This non-HPV substance is also referred to as monomer acid sodium salt in the Final Data Summary for Tall Oil Fatty Acids and Related Substances.
Method	
Method/Guideline followed	Test procedure was OECD Test Method 423, *"Acute Oral Toxicity- Acute Toxic Class Method"*
GLP (Y/N)	Y
Year (Study Performed)	2002
Species	Rat
Strain	Sprague-Dawley
Route of administration	Oral
Dose levels	2000 mg/kg
Sex and number/group	3 male and 3 female rats
Frequency of treatment	Single oral gavage
Duration of test	14 day observation post-treatment
Control group (Y/N)	N

Result	
Acute Oral LD_{50}	>2500 mg/kg
Detailed Summary	Sprague-Dawley rats (n = 3/sex) received a single oral (gavage) dose of 2000 mg/kg of monomer acid, sodium salt and were observed for 14 days. Parameters evaluated included clinical signs, mortality, body weight, and gross pathology. None of the animals died. No body weight effects were observed. Gross necropsy revealed no treatment-related effects. The acute oral LD_{50} was estimated as being greater than 2500 mg/kg.
Data Quality	Valid without restriction – Klimisch Code 1a
Reference	Sanders, A. 2002. Acute oral toxicity study in the rat – Acute Toxic Class Method. Project No. 1078/031. SafePharm Laboratories, Derby, UK.

ACUTE TOXICITY – ORAL	
Test substance	
Chemical Name	Fatty acids, C16-C18 and C18 unsaturated, branched and linear, calcium salt
CAS #	Not assigned
Remarks	This non-HPV substance is also referred to as monomer acid calcium salt in the Final Data Summary for Tall Oil Fatty Acids and Related Substances.
Method	
Method/Guideline followed	Test procedure was OECD Test Method 423, *"Acute Oral Toxicity- Acute Toxic Class Method"*
GLP (Y/N)	Y
Year (Study Performed)	2002
Species	Rat
Strain	Sprague-Dawley
Route of administration	Oral
Dose levels	2000 mg/kg
Sex and number/group	3 male and 3 female rats
Frequency of treatment	Single oral gavage
Duration of test	14 day observation post-treatment
Control group (Y/N)	N
Result	
Acute Oral LD_{50}	>2500 mg/kg
Detailed Summary	Sprague-Dawley rats (n = 3/sex) received a single oral (gavage) dose of 2000 mg/kg of monomer acid, calcium salt and were observed for 14 days. Parameters evaluated included clinical signs, mortality, body weight, and gross pathology. None of the animals died. No body weight effects were observed. Gross necropsy revealed no treatment-related effects. The acute oral LD_{50} was estimated as being greater than 2500 mg/kg.
Data Quality	Valid without restriction – Klimisch Code 1a
Reference	Sanders, A. 2002. Acute oral toxicity study in the rat – Acute Toxic Class Method. Project No. 1078/031. SafePharm Laboratories, Derby, UK.

REPEAT DOSE TOXICITY	
Test substance	
Chemical Name	Tall oil fatty acid
CAS #	61790-12-3
Remarks	This substance is also referred to as TOFA in the Final Data Summary for Tall Oil Fatty Acids and Related Substances.
Method	
Method/Guideline followed	Test procedure was similar to OECD Test Method 407, *"Repeat Dose 28-Day Oral Toxicity Study in Rodents,"* but failed to collect data on several parameters (hematology, clinical chemistry, histopathology) and was only conducted in male animals.
Year	1969
GLP (Y/N)	N (pre-GLP)
Species	Rat
Strain	Sprague-Dawley
Sex	Male
Route of Administration	Oral, diet
Exposure Period	28 days
Frequency of Treatment	Daily
Post-exposure observation period	None
Dose Levels	0, 15, 30, and 60% of total calories
Control group (Y/N)	Y
Results	
NOAEL:	15%
Detailed Summary	Male Sprague-Dawley rats (n = 10/group) were fed diets containing tall oil acid distillate (CAS #61790-12-3) as 0, 15, 30 or 60% of the total calories for four weeks. Parameters evaluated included mortality, body weight, and food consumption. One animal treated with 15% died (day of death not specified) and all animals treated with 60% died within four days of dose initiation. It is unlikely that this single death was a treatment related effect since similar mortality did not occur at 30%. No effect on growth rate was reported at 15%, but a significant decrease in growth was reported at 30%.
Data Quality	Not assignable – Klimisch Code 4b
Reference	Seppanen 1969 as cited in: Anon. 1989. Final report on the safety assessment of tall oil acid. J. Amer. Coll. Toxicol. 8:769-776.

REPEAT DOSE TOXICITY	
Test substance	
Chemical Name	Tall oil fatty acid
CAS #	61790-12-3
Remarks	This substance is also referred to as TOFA in the Final Data Summary for Tall Oil Fatty Acids and Related Substances.
Method	
Method/Guideline followed	Test procedure is consistent with OECD Test Method 407, *"Repeat Dose 28-Day Oral Toxicity Study in Rodents"*
Year	1969
GLP (Y/N)	N (pre-GLP)
Species	Rat

Strain	Charles River
Sex	Male, female
Route of Administration	Oral, diet
Exposure Period	90 days
Frequency of Treatment	Daily
Post-exposure observation period	None
Dose Levels	5, 10, and 25% (approximately equivalent to 2500, 5000, and 12,500 mg/kg/day)
Control group (Y/N)	Y
Results	
NOEL:	5%, approximately 2500 mg/kg/day
Detailed Summary	Tall oil fatty acid was administered to Charles River rats (n = 10/sex/group) in the diet at concentrations 0, 5, 10, or 25% for 90 days. The approximate doses were 0, 2,500, 5,000, or 12,500 mg/kg/day, based on standard conversion factors provided by WHO (1990). Parameters evaluated included clinical signs, mortality, body weight, body weight gain, food consumption, hematology, clinical chemistry, urinalysis, gross pathology, organ weights (liver, kidneys, spleen, gonads, heart, adrenal glands, thyroid gland, brain), and microscopic pathology (esophagus, stomach, small intestine, cecum, colon, liver, kidneys, spleen, pancreas, urinary bladder, pituitary gland, adrenal gland, testes, seminal vesicle, ovary, bone marrow, thyroid gland, parathyroid gland, salivary gland, prostate gland, heart, aorta, lung, lymph node, skeletal muscle, peripheral nerve, bone, spinal cord, uterus, trachea, eye, optic nerve, brain). Two control rats died during blood sampling. No other deaths occurred and no clinical signs were observed. Body weight and body weight gain were not affected by treatment, but food consumption was slightly decreased at 10 and 25%. No changes in hematology, clinical chemistry or urinalysis parameters occurred at any dose. At gross pathology, no treatment-related effects were noted at any dose. No consistent organ weight changes and no histopathological effects were reported at any dose. Based on these data, the NOEL was 5% (approximately 2,500 mg/kg/day).
Data Quality	Valid without restriction – Klimisch Code 1b
References	Fancher, O.E. 1969. Ninety-day subacute oral toxicity of [trade name deleted; tall oil fatty acid] in albino rats. IBT No. B7067. Industrial Bio-Test Laboratories, Inc., Northbrook, Illinois. World Health Organization (WHO). 1990. Principles for the Toxicological Assessment of Pesticide Residues in Food.

IN VITRO GENETIC TOXICITY	
Test substance	
Chemical Name	Tall oil fatty acid
CAS #	61790-12-3
Remarks	This substance is also referred to as TOFA in the Final Data Summary for Tall Oil Fatty Acids and Related Substances.
Method	
Method/Guideline followed	Test was consistent with OECD Test Method 471, *"Bacterial*

	Reverse Mutation Test"
Year	1984
GLP (Y/N)	Y
System of testing	*S. typhimurium* strains TA98, TA100, TA1535, TA1537, TA1538
Concentration	0, 100, 333, 1000, 3333, 10000 µg/plate
Metabolic activation	With and without addition of S-9 fraction from Aroclor 1254-treated Sprague-Dawley rats.
Results	Non-mutagenic
Detailed Summary	Tall oil fatty acid was tested against *S. typhimurium* strains TA98, TA100, TA1535, TA1537 and TA1538 for mutagenic activity. The test article was tested at concentrations of 100, 333, 1000, 3333 and 10,000 µg/plate with and without metabolic activation with S-9 fraction. Positive controls not requiring metabolic activation included sodium azide, 9-aminoacridine and 2-nitrofluorene; the positive control requiring metabolic activation was 2-aminoanthracene. No increases in mutation frequency were reported at any concentration of tall oil fatty acid with or without metabolic activation. Tall oil fatty acid was not mutagenic in this assay.
Data Quality	Valid without restriction – Klimisch Code 1a
Reference	Godek, E.G. 1983. Ames Salmonella/microsome plate test: fatty acid [trade name deleted]. Study No. PH 301D-AC-018-83. Pharmakon Research International, Inc., Waverly, Pennsylvania.

IN VITRO GENETIC TOXICITY	
Test substance	
Chemical Name	Fatty acids, C16-C18 and C18 unsaturated, branched and linear, sodium salt
CAS #	Not assigned
Remarks	This substance is also referred to as monomer acid sodium salt in the Final Summary document for Tall Oil Fatty Acids and Related Substances.
Method	
Method/Guideline followed	OECD Test Method 471, *"Bacterial Reverse Mutation Test"*
Year	2002
GLP (Y/N)	Y
System of testing	*S. typhimurium* strains TA98, TA100, TA102, TA1535 and TA15378
Concentration	50, 150, 500, 1500, and 5000 µg/plate
Metabolic activation	With and without addition of S-9 fraction from phenobarbitone/â-naphthoflavone-treated Sprague-Dawley rats.
Results	Non-mutagenic with or without metabolic activation
Detailed Summary	Monomer acid sodium salt was tested against *S. typhimurium* strains TA98, TA100, TA102, TA1535 and TA1537 for mutagenic activity at concentrations of 50, 150, 500, 1500 and 5000 µg/plate with and without metabolic activation. Positive controls not requiring metabolic activation included N-ethyl-N-nitro-N-nitrosoguanidine, mytomycin C, , 4-nitroquinoline-1-oxide and 9-aminoacridine; the positive controls requiring metabolic activation were 2-aminoanthracene, benzo(a)pyrene, and 1,8-dihydroxyanthraquinone. No increases in mutation frequency were reported at any concentration of monomer acid sodium salt with or without metabolic activation. Monomer acid sodium salt

	was not mutagenic in this assay either with or without metabolic activation.
Data Quality	Valid without restriction – Klimisch Code 1a
Reference	Thompson, P.W. 2002. [Monomer Acid Sodium Salt] Reverse Mutation Assay "Ames Test" Using *Salmonella Typhimurium*. Proj. No. 1078/038. SafePharm Laboratories, Derby, UK.

IN VITRO GENETIC TOXICITY	
Test substance	
Chemical Name	Tall oil fatty acid
CAS #	61790-12-3
Remarks	This substance is also referred to as TOFA in the Final Data Summary for Tall Oil Fatty Acids and Related Substances.
Method	
Method/Guideline followed	OECD Test Method 473, *"Chromosomal Aberration Assay with Chinese Hamster Ovary Cells in vitro."*
Year	2001
GLP (Y/N)	Y
System of testing	Chinese Hamster Ovary (CHO) cells *in vitro*
Concentration	With S9 mix: 5, 10 and 20 ug/ml Without S9 mix: 39, 78 and 156 ug/ml
Metabolic activation	With and without addition of S-9 fraction from Aroclor 1254-treated adult male Fisher rats.
Results	Clastogenic with S9 mix at 20 ug/ml and without S9 mix at 156 ug/ml; both concentrations were overtly toxic to the cells.
Detailed Summary	Tall oil fatty acid was tested in Chinese hamster ovary (CHO) cells for clastogenic activity both with and with metabolic activation with rat liver S9 mix. The test article was tested with metabolic activation with S9 mix at concentrations of 5, 10 and 20 ug/ml and without metabolic activation with S9 mix at concentrations of 39, 78 and 156 ug/ml. The positive controls requiring and not requiring metabolic activation were cyclophosphamide (CPH) and methanesulphonate (MMS), respectively. Treatments with test item or controls were performed on duplicate cell cultures. Two slides per culture up to 50 metaphase cells per slide were examined. A dose level was considered to be toxic if the cell count was reduced to less than 50% of the mean vehicle control values or if consistent evidence of changes to cell morphology was observed. In both the presence and absence of S9 mix, positive levels of structural aberrations were observed. In the presence of S9 mix, this response was observed in the cultures treated with 20 ug/ml and in the absence of S9 mix, in the cultures treated with 156 ug/ml. Both of these concentrations were judged overtly toxic to the cultures. Therefore, tall oil fatty acid was a clastogen at toxic concentrations.
Data Quality	Valid without restriction – Klimisch Code 1a
Reference	Murie, E. 2001. Fatty Acids, CAS No. 61790-12-3 Chromosomal Aberration Assay with Chinese Hamster Ovary Cells in vitro (Complying with EC (Annex V) and OECD 473 Guidelines). Report No. 20712. Inveresk Research, Tranent, Scotland.

IN VITRO GENETIC TOXICITY	
Test substance	
Chemical Name	Fatty acids, C16-C18 and C18 unsaturated, branched and linear, calcium salt
CAS #	Not assigned
Remarks	This substance is also referred to as monomer acid calcium salt in the Final Summary document for Tall Oil Fatty Acids and Related Substances.
Method	
Method/Guideline followed	OECD Test Method 473, *"Genetic Toxicology: Chromosomal Aberration Test."*
Year	2002
GLP (Y/N)	Y
System of testing	Human lymphocytes *in vitro*
Concentration	With S9 mix: 0, 31.25, 62.5, 125, 250, 375 and 500 ug/ml Without S9 mix: 0, 31.25, 62.5, 125, 250, 375 and 500 ug/ml
Metabolic activation	With and without addition of S-9 fraction from phenobarbitone/â-naphthoflavone-treated male Sprague-Dawley rats.
Results	Monomer acid calcium salt was non-clastogenic to human lymphocytes *in vitro* both with and without metabolic activation.
Detailed Summary	Monomer acid calcium salt was tested *in vitro* in human lymphocyrtes for clastogenic activity both with and with metabolic activation with rat liver S9 mix. Lymphocytes were obtained from a volunteer who had been previously sereened for suitability (not exposed to radiation, hazardous chemicals or recently suffereing from a viral infection). Cells were grown in Eagle's minimal essential medium with HEPES buffer, supplemented with L-glutamine, penicillin/streptomycin, amphotericin B and 15% fetal calf serum. Following a preliminary toxicity rangefinding test, the test article was tested both with and without metabolic activation with S9 mix at concentrations of 0, 31.25, 62.5, 125, 250, 375 and 500 ug/ml. The positive controls requiring and not requiring metabolic activation were cyclophosphamide and mitomycin C, respectively. A total of 2000 lymphocyte cell nuclei were counted and the number of cells in metaphase recorded and expressed as the mitotic indec and as a percentage of the vehicle control value. Due to cellular toxicity the maximum dose level selected for metaphase analysis was 150 ug/ml in both exposure groups. The test material did not induce a toxicologically significant increase in the frequency of cells with chromosomal aberrations in either the absence or presence of a liver enzyme metabolizing system in either of two separate experiments. Monomer acid calcium salt was therefore considered to be non-clastogenic to human lymphocytes *in vitro*.
Data Quality	Valid without restriction – Klimisch Code 1a
Reference	Jenkinson, P.C. and Durward, R. 2002. [Monomer acid calcium salt] Chromosomal Aberration Test in Human Lymphocytes *In* Vitro. SPL Proj. No. 1078/086. SafePharm Laboratories, Derby, UK.

REPRODUCTION AND DEVELOPMENTAL TOXICITY	
Test substance	
Chemical Name	Tall oil fatty acid
CAS #	61790-12-3
Remarks	This substance is also referred to as TOFA in the Final Data Summary for Tall Oil Fatty Acids and Related Substances.
Method	
Method/Guideline followed	Test procedure was consistent with OECD Test Method 416, *"Two-Generation Reproduction Toxicity Study"* with one exception: the initial treatment period was decreased (three weeks versus ten weeks).
Year	1975
GLP (Y/N)	N
Species	Rat
Strain	Sprague-Dawley
Sex	Male and female
Route of Administration	Oral, diet
Frequency of Treatment	Daily
Dose	5 and 10% (approximately equivalent to 2500 and 5000 mg/kg/day)
Control group (Y/N)	Y
Pre-mating exposure period for males	20 days (parental generation)
Pre-mating exposure period for females	20 days (parental generation)
Results	
NOEL	10%, approximately 5000 mg/kg/day, for reproductive and systemic toxicity
Detailed Summary	Sprague-Dawley rats (n = 30 females/group and 15 males/group) were administered tall oil fatty acid (CAS #61790-12-3) in the diet at concentrations of 0, 5 or 10%. The approximate doses were 0, 2,500, or 5,000 mg/kg/day, based on standard conversion factors provided by WHO (1990). The parental (F_0) generation began treatment at 80 days of age and were mated at 100 days of age. Treatment continued through the weaning of the first generation (F_1). After weaning, 20 F_1 males and 20 F_1 females per group were maintained on the parental diet. At 100 days of age, these rats were mated and allowed to deliver pups (F_2). Parameters evaluated included F_1 reproductive parameters, F_1 fertility, viability, lactation, and gestation indices, hematology, serum chemistry, urinalysis, and microscopic pathology of the F_2 pups (brain, pituitary gland, spinal cord, eye, sub-maxillary gland, thyroid, lungs, heart, liver, kidneys, spleen, adrenals, pancreas, stomach, intestines, lymph nodes, bladder, gonads, skin, bone, bone marrow, nerve, muscle). Treatment did not affect the number of liveborn or stillborn F_1 litters and pups, or F_1 weaning weight. No treatment-related changes in fertility, viability, lactation, or gestation indices were measured. Hematology, clinical chemistry and urinalysis parameters were similarly unchanged, and gross and microscopic pathology revealed no treatment-related effects. Tall oil fatty acid had no effect on the reproductive or developmental capabilities of rats at doses as high as 10% (approximately 5,000 mg/kg/day).

Data Quality	Valid without restriction – Klimisch Code 1b
References	Tegeris, A.S. 1975. Sub-acute reproduction in the rat on tall oil fatty acid [trade name deleted]. Report No. 75-106. Pharmacopathics Research Laboratories, Inc., Laurel, Maryland. World Health Organization (WHO). 1990. Principles for the Toxicological Assessment of Pesticide Residues in Food.

REPRODUCTION AND DEVELOPMENTAL TOXICITY	
Test substance	
Chemical Name	Tall oil fatty acid
CAS #	61790-12-3
Remarks	This substance is also referred to as TOFA in the Final Data Summary for Tall Oil Fatty Acids and Related Substances.
Method	
Method/Guideline followed	Test procedure was consistent with OECD Test Method 416, *"Two-Generation Reproduction Toxicity Study"* with one exception: the initial treatment period was decreased (three weeks versus ten weeks).
Year	1977
GLP (Y/N)	N
Species	Rat
Strain	Sprague-Dawley
Sex	Male and female
Route of Administration	Oral, diet
Frequency of Treatment	Daily
Dose	5 and 10% (approximately equivalent to 2500 and 5000 mg/kg/day)
Control group (Y/N)	Y
Pre-mating exposure period for males	20 days (parental generation)
Pre-mating exposure period for females	20 days (parental generation)
Results	
NOEL	10%, approximately 5000 mg/kg/day, for reproductive and systemic toxicity
Detailed Summary	Sprague-Dawley rats (n = 30 females/group and 15 males/group) were administered tall oil fatty acid (CAS #61790-12-3) in the diet at concentrations of 0, 5 or 10%. The approximate doses were 0, 2,500, or 5,000 mg/kg/day, based on standard conversion factors provided by WHO (1990). The parental (F_0) generation began treatment at 80 days of age and were mated at 100 days of age. Treatment continued through the weaning of the first generation (F_1). After weaning, 20 F_1 males and 20 F_1 females per group were maintained on the parental diet. At 100 days of age, these rats were mated and were allowed to deliver pups (F_2). The F_2 generation survived to weaning. Parameters evaluated included F_1 reproductive parameters, F_1 fertility, viability, lactation, and gestation indices, hematology, serum chemistry, urinalysis, organ weights for F_1 animals (thyroids, heart, liver, adrenals, kidneys, gonads), gross pathology of F_1 and F_2 animals, and microscopic pathology of the F_2 pups (brain, pituitary gland, spinal cord, eye, sub-maxillary gland, thyroid, lungs, heart, liver, kidneys, spleen,

	adrenals, pancreas, stomach, intestines, lymph nodes, bladder, gonads, skin, bone, bone marrow, nerve, muscle). There were no treatment effects on reproductive performance, the number of liveborn or stillborn F_1 litters and pups, or weaning weight of the F_1 pups. No treatment-related changes in fertility, viability, lactation, or gestation indices were measured. Hematology, clinical chemistry and urinalysis parameters were similarly unchanged, organ weights were unchanged, and gross and microscopic pathology revealed no treatment-related effects. Tall oil fatty acid had no effect on the reproductive or developmental capabilities of rats at doses as high as 10% (approximately 5,000 mg/kg/day).
Data Quality	Valid without restriction – Klimisch Code 1b
References	Tegeris, A.S. 1977. Tall oil fatty acid: two-generation reproduction study in the rat. Report No. 77-124. Pharmacopathics Research Laboratories, Inc., Laurel, Maryland. World Health Organization (WHO). 1990. Principles for the Toxicological Assessment of Pesticide Residues in Food.